Decision Memo for Implantable Defibrillators - Clinical Trials (CAG-00157R)

Decision Summary

CMS concludes that outside the covered indications it is appropriate to allow coverage of implantable defibrillators in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201) or as a routine cost in clinical trials defined under the NCD Manual section 310.1. Therefore, CMS will allow coverage under these circumstances as outlined in the policy (NCD 20.4).

Back to Top

Decision Memo

To: Administrative File CAG: # 00157R
Implantable Cardioverter Defibrillators

From:

Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group

Marcel Salive, MD, MPH
Director, Division of Medical and Surgical Services

JoAnna F. Baldwin
Health Insurance Specialist, Division of Medical and Surgical Services

Joseph Chin, MD, MS
Medical Officer, Division of Medical and Surgical Services

Subject: National Coverage Determination (NCD) on Implantable Defibrillators

Date: March 12, 2004

I. Decision

CMS concludes that outside the covered indications it is appropriate to allow coverage of implantable defibrillators in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201) or as a routine cost in clinical trials defined under the NCD Manual section 310.1. Therefore, CMS will allow coverage under these circumstances as outlined in the policy (NCD 20.4).

II. Background

On June 6, 2003, CMS posted a national coverage determination (NCD) memorandum announcing its decision to modify CIM 35-85 Implantation Of Automatic Defibrillators to add additional indications for implantation. The memorandum added the phrase "All other indications are also noncovered." Soon after publishing this memorandum CMS determined that this phrase may have prevented the CMS contractors from providing coverage for unlisted indications in clinical trials, including those currently underway that currently have contractor coverage. That was not the intended result. Therefore, when CMS issued the NCD coverage instruction in August 2003 we included language that would allow coverage of implantable defibrillators in Category B IDE clinical trials (60 CFR 48417) or as a routine cost in clinical trials defined under CIM 30-1 (NCD 130.1). This reconsideration allows CMS to discuss in depth the reasoning behind the inclusion of that language in the coverage instruction.

III. History of Medicare Coverage

The Centers for Medicare & Medicaid Services (CMS), issued a Medicare National Coverage Determination in 1986 providing limited coverage of implantable defibrillators. The policy has expanded over the years with revisions in 1991, 1999, and 2003. Guidant Corporation requested the reconsideration that resulted in the 2003 policy revision. This reconsideration was based on the results of the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) and led to an expansion of coverage to include MADIT II type patients with a QRS duration of > 120 milliseconds. The decision memorandum that outlines the reasoning for this change is available on our website and can be found at www.cms.gov/coverage.

IV. Timeline of Recent Activities

June 6, 2003	CMS publishes the decision memorandum announcing an expansion in Medicare coverage to include patients with a previous MI, low LVEF, and long QRS. This document announced that all indications not listed in the document as covered would be noncovered.
August 1, 2003	CMS opens a reconsideration of CIM 35-85 to allow otherwise noncovered indications to be covered in the context of IDE Category B clinical trials and as the routine cost under the clinical trials policy.
August 25, 2003	CMS publishes National Coverage Determination for the original review of implantable defibrillators. This document includes language to allow for coverage of noncovered indications in Category B IDE trials and as a routine costs under the clinical trials policy.
August 31, 2003	Public comment period for the reconsideration closed.
October 1, 2003	Expanded indications become effective.

V. Evidence

Current Clinical Trials

CMS understands that if language in the June 6, 2003 decision memorandum were implemented, we might have significantly impacted clinical trials. This impact could have halted trials currently underway or cancelled trials scheduled to start in the near future. CMS is aware of ongoing and upcoming clinical trials that have endpoints important to CMS. Ensuring that these trials continue increases the level of evidence available so that coverage policy can be refined and adjusted through evidence based medicine.

Expert and Public Comments

CMS received comments cosigned by NASPE Heart Rhythm Society and the American College of Cardiology. They support CMS's intention to allow coverage of implantable defibrillators in current and future clinical trials. The letter notes that if the policy were not changed, at least seven clinical trials would be adversely impacted.

Medtronic Inc. submitted comments in support of this change to the decision. They comment that this change will encourage the inclusion of Medicare beneficiaries in trials.

St. Jude Medical commented on the unforeseen hardship CMS could have caused for patients currently enrolled in clinical trials had they not allowed coverage in trials. The company supports allowing coverage for implantable defibrillators in clinical trials.

Comments submitted by the FDA show support for this coverage decision. The FDA suggests that further studies will help to clarify the most beneficial use of implantable defibrillators.

VI. CMS Analysis

In our June 6, 2003 Decision Memorandum, we considered Medicare coverage of implantable defibrillators, including the issue of whether implantable defibrillators were "reasonable and necessary" in accordance with section 1862(a)(1)(A) of the Social Security Act. We reviewed whether the clinical evidence supported a finding that implantable defibrillators were reasonable and necessary and we set forth a list of covered indications. We are not revisiting that analysis except with respect to coverage in clinical trials. In that Decision Memorandum, we indicated that all indications not specifically listed as covered would be non-covered. But we did not intend to exclude coverage in accordance with CMS policies concerning clinical trials. Moreover, we found no clear evidence that might specifically warrant non-coverage in clinical trials (such as harm to patients, improper use, or ineffectiveness). Thus, we do not believe our prior analysis indicated any reason to exclude coverage of implantable defibrillators for unlisted indications in appropriate clinical trials when that coverage is consistent with CMS policies concerning clinical trials.

In sum, CMS did not intend for the language in the June 6, 2003 decision memorandum to adversely impact current and future clinical trials studying implantable defibrillators. Some of the studies underway could provide critical information to CMS and the medical community concerning appropriate implantation of the device.

Therefore, CMS concludes that outside the covered indications it is appropriate to allow coverage of implantable defibrillators in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201) or as a routine cost in clinical trials defined under the NCD Manual section 310.1. Therefore, CMS will allow coverage under these circumstances.

Back to Top